

DATE 11-21-11

APPLICATION NUMBER 07/841617

DOC CODE TERM-PTO.LTI

DOC DATE 11-21-11

DELIVER THE ATTACHED FILE/DOCUMENT TO THE TC  
SCANNING CENTER

CONTRACTOR: THE ATTACHED FILE/DOCUMENT MUST BE  
INDEXED AND SCANNED INTO IFW WITHIN 8 WORK HOURS;  
UPLOADING OF THE SCANNED IMAGES SHOULD OCCUR NO  
LATER THAN 16 WORK HOURS  
FOLLOWING RECEIPT OF THIS REQUEST

: AFTER SCANNING, ORIGINAL DOCUMENTS SHOULD BE BOXED IN  
ACCORDANCE WITH INSTRUCTIONS



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
www.uspto.gov

NOV 21 2011

Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,310,912. The application was filed on March 7, 2011, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Tili  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner  
for Patent Examination Policy

cc: Christine S. Lee  
Intellectual Property Counsel  
GE Healthcare  
101 Carnegie Center  
Princeton, NJ 08540

RE: DaTscan (Ioflupane I-123 Injection)  
Docket No. FDA-2011-E-0367